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OIL STATES ENERGY SERVICES, LLC,
Petitioner,
v.
GREENE'S ENERGY GROUP, LLC, ET AL.,
Respondents.

ON WRIT OF CERTIORARI TO THE
U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF AMICUS CURIAE THE INITIATIVE FOR MEDICINES, ACCESS & KNOWLEDGE (I-MAK) IN SUPPORT OF RESPONDENTS

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES ii

INTEREST OF AMICUS CURIAE 1

SUMMARY OF ARGUMENT 2

ARGUMENT 3

I. *INTER PARTES* REVIEW IS ESSENTIAL FOR LOWERING PHARMACEUTICAL DRUG COSTS 3

A. Unmerited Patents Contribute to High Drug Costs 5

1. Pharmaceutical Companies Spend More on Lobbying and Marketing Than on Research and Development 5

2. Unmerited Secondary Patents Stifle Generic Competition and Inflate Drug Prices 7

B. *Inter Partes* Review is Critical to Lowering Drug Costs 16

II. ELIMINATING *INTER PARTES* REVIEW WOULD REVERSE EARLY PROGRESS TOWARDS REDUCED DRUG COSTS 19

CONCLUSION 20

TABLE OF AUTHORITIES

Page(s)

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INTEREST OF AMICUS CURIAE*

The Initiative for Medicines, Access & Knowledge ("I-MAK") is a not-for-profit charitable organization, comprised of lawyers, scientists, and health experts interested in increasing access to affordable medicines by restoring integrity to the patent system. I-MAK is committed to challenging, repairing and ultimately redesigning the patent system to ensure that consumers worldwide can obtain the lifesaving medications that they need. I-MAK helps patients, consumers, governments, and patent offices create systems that support a competitive market where the needs of patients and payers are equally represented.

To advance the public interest by reducing drug costs and increasing access to affordable, lifesaving medicines, I-MAK files petitions for *Inter Partes* Review of unmerited patents stifling competition to life-saving pharmaceuticals.

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* No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than amicus curiae, its members, or its counsel made a monetary contribution to its preparation or submission. The parties have issued blanket consents to the filing of amicus briefs.

SUMMARY OF ARGUMENT

In 2011, Congress passed the Leahy-Smith America Invents Act ("AIA") to curb the spread of unmerited patents, stop abusive litigation, and ensure a fair playing field for patent applicants. Leahy-Smith America Invents Act, Pub. L. No. 112-20, 125 Stat. 284, 35 U.S.C. § 1 *et seq.* (2011). In the face of industry overreliance on patenting, the AIA took a major step towards restoring the integrity and strength of the U.S. patent system. Specifically, the legislation created an administrative framework known as *inter partes* review ("IPR") to ensure that patent monopolies are restricted to their legitimate scope. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144 (2016).

As a "specialized agency proceeding," IPR enables the United States Patent and Trademark Office ("PTO"), through the Patent Trial and Appeals Board ("PTAB"), to reevaluate its initial patentability decision and cancel unpatentable claims. *Id.* at 2143-44; *see* 35 U.S.C. § 316(c). Third-parties may request this procedure, and each case is heard by a panel of three judges who are experts in the patent field. This administrative framework promotes public participation and transparency in the U.S. patent system, and the PTAB has established itself as an effective and efficient arbitrator.

This brief articulates the policy rationales in favor of administrative review. In particular, IPR is crucial for the elimination of unmerited patents, which enable certain corporations to unfairly over-monopolize the pharmaceutical market. To increase profits, pharmaceutical companies routinely seek secondary patents that extend their drug's

exclusivity period. A substantial portion of these patents are based on well-known scientific principles that have been in the public domain for decades. As such, many secondary patents are unmerited and do not satisfy the pertinent legal requirements. Instead, these patents seek to stifle competition from other drug manufacturers without providing further scientific advancements to the pharmaceutical field and the public. Extended exclusivity periods create prolonged monopolies which, in turn, contribute to rising drug costs.

The PTAB, however, represents one of the patent system's most fundamental checks and balances. As an administrative body, the PTAB promotes the timely and efficient resolution of patent challenges without the delays and costs associated with litigation. The expedient review afforded by the PTAB through IPR is crucial to reduce the high cost of pharmaceutical drugs. IPR, therefore, is an important and necessary tool in the fight to lower drug prices because it allows the timely removal of unmerited patents, which promotes competition.

ARGUMENT

I. *Inter Partes* Review is Essential for Lowering Pharmaceutical Drug Costs.

Americans are facing a prescription affordability crisis that can no longer be denied. One in five households have reported not being able to fill a prescription in the last year due to the high costs of medicines. *Kaiser Health Tracking Poll: Health Care Priorities for 2017.* (2017) The Henry J. Kaiser Family Foundation, https://www.kff.org/healthcosts/poll-finding/kaiser-

health-tracking-pollhealth-care-priorities-for-2017/. Seventy per cent of American voters across the political spectrum identified prescription drug pricing as a critical problem *The public's views of tax reform and other domestic issues.* (September 2017), Politico /Harvard T.H. Chan School of Public Health, **http://www.politico.com/f/?id=0000015e-a4d7-d873-adfe-bdd740140000**

It is no wonder there are such concerns from the public as the cost index for branded drug prices has nearly tripled from 2008 to 2016. *What is the recent and forecasted trends in prescription drug spending?* Peterson-Kaiser Health System Tracker. (22 May 2017), **https://www.healthsystemtracker.org/chartcollection/recent-forecasted-trends-prescriptiondrug-spending**.

The total annual prescription drug spending is poised to double by 2025. See R Kamal and C Cox, *2016-2025 Projections of National Health Expenditures.* Centers for Medicare and Medicaid Services, Office of the Actuary. (15 Feb 2017)

Faced with this stark reality, Americans are uniting against pharmaceutical monopolies, with over 80% of Democrat and Republican voters calling for decreased drug prices. I-MAK, Policy Brief: How the Supreme Court Patent Case Could Raise Drug Prices 1, *available at* http://www.i-mak.org/scotus-policy-brief/ [hereinafter I-MAK Policy Brief]; *see also Americans' Top Priorities for Congress Through the End of the Year,* Politico (Sept. 2017), https://www.politico.com/f/?id=0000015e-7bce-d079-a3fe-7bce31540000. While the battle for lower cost drugs is being waged on multiple fronts, its applicability to the IPR debate cannot be ignored. IPR is essential to the fight for reduced drug prices

because it ensures timely and efficient removal of unmerited patents that prolong pharmaceutical monopolies and, consequently, substantially reduce competition from other drug manufacturers. This section explains (A) how unmerited patents contribute to increased drug prices and (B) the IPR's role in helping to reduce pharmaceutical costs.

A. Unmerited Patents Contribute to High Drug Costs.

To understand the PTAB's role in reducing drug prices, it is essential to comprehend how patents contribute to high pharmaceutical drug costs. Through comprehensive research and analysis, I-MAK discovered that unmerited patents are a root cause of high drug prices. *See* I-MAK Policy Brief, *supra*, at 1. In particular, I-MAK found that a key reason drug prices are so unaffordable is that pharmaceutical companies over-patent lifesaving drugs without new inventions that justify the exclusivity they are granted. *Id.* For many corporations, over-patenting tactics are simply a way to prolong their monopolies by preventing, for example, , lower-cost generic equivalents from entering the marketplace.

1. Pharmaceutical Companies Spend More on Share Buybacks and Lobbying Than on Research and Development.

U.S. pharmaceutical invention and ingenuity has drastically declined in recent years. During the past decade, the country's biggest pharmaceutical companies have spent more on share buybacks and

lobbyists than they have on new research and development. *Id.* at 2. According to a recent study by the Institute for New Economic Thinking, between 2006 and 2015, the 18 drug corporations in Standard & Poor's 500 index spent more than $516 billion on buybacks and dividends, compared to $465 billion on research and development. *See* William Lazonick et al., U.S. Pharma's Financialized Business Model (July 13, 2017), *available* at https://www.ineteconomics.org/research/research-papers/us-pharmas-financialized-business-model. Biogen Idec, for example, spent $14.6 billion on stock buybacks, compared to $13.8 billion on research and development. *Id.*; I-MAK Policy Brief, *supra*, at 2. Similarly, Gilead spent $27 billion on buybacks, compared with $17 billion on research and development. *See* I-MAK Policy Brief, *supra*, at 2.

Meanwhile, pharmaceutical and health lobbying spending continues to increase. In the first quarter of 2017, spending in these areas reached $78 million. Eric Lipton & Katie Thomas, *Drug Lobbyists' Battle Cry Over Prices: Blame the Others*, N.Y. Times (May 29, 2017), https://www.nytimes.com/2017/05/29/health/drug-lobbyists-battle-cry-over-prices-blame-the-others.html. The Pharmaceutical Researchers and Manufacturers of America, the industry's largest advocate, and the Biotechnology Innovation Organization spent more money lobbying Congress and the Trump administration in the first six months of 2017 than they have in that period since 1999. *Pharmaceuticals/Health Products Industry Profile: Summary, 2017*, Open Secrets, https://www.opensecrets.org/lobby/indusclient.php?id=H04&year=2017 (last updated Oct. 21, 2017). These

trends create a vicious cycle in which companies allow the pipeline of novel and non-obvious products to take a backseat due, in part, to Wall Street investors' and shareholders' expectations of ever-higher returns. Pharmaceutical companies thus spend more money lobbying *against* measures that would rein in drug prices. I-MAK Policy Brief, *supra*, at 2.

Accordingly, the pursuit of patent exclusivity is no longer fueled by science and technology that pushes the boundaries of existing knowledge. Instead, pharmaceutical companies have transformed the patent system into a tool for immediate profits that offers maximum returns with the least amount of effort.

2. Unmerited Secondary Patents Stifle Competition and Increase Drug Costs.

The pharmaceutical industry's profit scheme is particularly evident in the proliferation of secondary patents. Whereas patents on active pharmaceutical ingredients are referred to as primary patents, secondary patents are filed on other aspects of the active ingredients, such as prodrugs, dosages, polymorphs, formulations, and production methods. Secondary patents often do not represent new scientific developments, but instead are used by pharmaceutical originator companies to extend patent protections on drugs in length and breadth. Given that every additional new patent grants 20 more years of exclusivity, corporations frequently and continuously file applications for secondary patents on the same drugs, opening the door to an effectively unlimited timeframe of exclusivity.

Unmerited secondary patents, therefore, allow pharmaceutical companies to artificially inflate the value of a "new" version of the same product instead of investing in true innovation and encouraging competition.

Significant increases in rates of secondary patenting have been documented in the United States following the introduction of the Hatch-Waxman Act in 1984. The Hatch-Waxman Act created new measures for generic drug entry, including provisions for challenging patents that block generic entry into the market. A study by Hemphill and Sampat found that the number of patents granted on medicines approved between 2000 and 2002 "roughly doubled" when compared with medicines approved between 1985 and 1987. C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 Science 1386-87 (Mar. 22, 2013). A separate review of patents granted in the United States on new medicines registered by the Food and Drug Administration ("FDA") between 1988 and 2005 revealed that companies more consistently and aggressively pursue secondary patents on their best-selling products. Amy Kapczynski et al., *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, PLOS One (Dec. 5, 2012), *available at* http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0049470. This suggests that secondary patents "reflect deliberate attempts by branded firms to lengthen their monopoly for more lucrative drugs." *Id.*

A forthcoming study by Robin C. Feldman and Connie Wang confirm these conclusions. Feldman and Wang analyzed patents for all drugs approved for sale in the United States between 2005 and 2015. The researchers found that pharmaceutical companies would rather recycle and repurpose old medicines than develop new, innovative drugs. Robin C. Feldman & Connie Wang, *May Your Drug Price Be Ever Green* (forthcoming 2017), https://papers.ssrn.com/sol3/cf_dev/AbsByAuth.cfm?per_id=179362. For each year studied, at least 74% of the drugs associated with new patents in the FDA's records were not new drugs, but instead were minor tweaks on existing medications. *Id.* This finding was particularly pronounced among blockbuster drugs. *Id.* Of the approximately 100 best-selling drugs, almost 80% had their protections extended at least once through secondary patenting or other FDA exclusivities, and 50% had two or more such extensions. *Id.* Looking at the data as a whole, almost 80% of companies that sought exclusivity protections – such as patents – obtained more than one, and 47% of companies had four or more protections. *Id.* This problem has grown over time, with the number of drugs subject to a patent or exclusivity provision doubling during the timeframe studied. *Id.* Thus, secondary patenting is an undeniable reality that is increasing in scope.

Indeed, secondary patenting is so prevalent that it has become a crucial component of pharmaceutical marketing and advertising. As discussed, the pharmaceutical industry invests more money on lobbying and marketing its current products than it does in research and development of new medicines. I-MAK Policy Brief, *supra*, at 2. By

obtaining secondary patents as part of the marketing and advertising strategy, drug companies enable "product switching" or "product hopping," whereby prior to patent expiry, the pharmaceutical company withdraws the original marketed product and forces consumers to switch to a new version based on nothing more than minor tweaks to the old version.

Moreover, some pharmaceutical companies have begun engaging in legal gymnastics to block competition and keep prolonged monopolies on medicines. Most recently, Allergan assigned six patents on its top-selling drug, Restasis, to the Saint Regis Mohawk Tribe of upstate New York. John Conley, *Allergan Assigns Patents to Native American Tribe to Avoid Validity Challenge*, Genomics L. Rpt. (Oct. 11, 2017), https://www.genomicslawreport.com/index.php/2017/10/11/allergan-assigns-patents-to-native-american-tribe-to-avoid-validity-challenge/. The sole purpose of this transfer was to take advantage of the tribe's claim to sovereign immunity, under which the tribe is immune from suit unless it consents or Congress abrogates its immunity. *Id.* By undertaking this action, Allergan hopes that generic competitors will be prevented from challenging the validity of the patents through IPR. *Id.*

To defend its actions, Allergan argues that the transfers protect the company against "double jeopardy" in patent disputes. Sy Mukherjee, *Botox Maker Allergan's CEO Defends Selling Drug Patents to Native American Tribe to Thwart Rivals*, Fortune (Sept. 9, 2017), http://fortune.com/2017/09/09/allergan-drug-patents-native-american/. Specifically, Allergan claims that it

can be sued for the same claim in both the district court and the PTAB. *Id.* This "double jeopardy" claim, however, is legally false. A party that files for IPR before the PTAB *cannot* file a lawsuit on the same grounds in court. That said, IPR is not meant to cover all possible patent claims, and it is possible that parallel litigation will proceed in court. This parallel litigation, however, does not encompass the same validity issues decided by the PTAB. Thus, Allergan's transfers preclude competition in a manner identical to – and, potentially, worse than – secondary patents.

Limitations on secondary patents and other exclusivity measures would deter such conduct by pharmaceutical companies. *FTC Files Amicus Brief Explaining that Pharmaceutical "Product Hopping" can be the Basis for an Antitrust Lawsuit*, Fed. Trade Comm'n (Nov. 27, 2012), https://www.ftc.gov/news-events/press-releases/2015/10/ftc-files-amicus-brief-explaining-pharmaceutical-product-hopping. In particular, pharmaceutical manufacturers would be less likely to spend significant amounts of money on advertising and marketing a new version of the product, which offers little or no added benefit to consumers. As a result, taxpayers and consumers would save significant resources.

Given this reality, it is unsurprising that secondary patents are hotly contested. While the pharmaceutical industry claims these patents are necessary for "incremental" innovation, evidence is increasingly showing that these patents, when challenged, are found invalid. In a 2013 review, Hemphill & Sampat collected information on

completed litigation on all drugs that first became eligible for challenges between 2000 and 2008. The litigation covered 277 patents and 147 drugs. Of the cases litigated to completion, branded companies were found to usually lose when asserting secondary patents (winning only 32% of cases). In other words, a generic company won 68% of completed litigation on secondary patents. *See* C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 Science 1386-87 (Mar. 22, 2013).

I-MAK's research confirms that pharmaceutical patents do not always meet the pertinent legal requirements. Drugs that are erroneously patented may be developed using previously published information, routine methods, and commonly practiced scientific techniques. The realities of the PTO's operations make erroneous patents inevitable. With approximately 9,000 examiners, the PTO reviews more than 500,000 patent applications each year – up from just 100,000 a couple of decades ago. Dennis Crouch, *USPTO's Swelling Examiner Rolls*, Patently-O (Nov. 30, 2014), https://patentlyo.com/patent/2014/11/usptos-swelling-examiner.html. Each week, the PTO grants approximately 6,000 new patents. *See* U.S. Patent & Trademark Office, U.S. Patent Statistics Chart Calendar Years 1963-2015, https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm (last updated Oct. 27, 2017). While a number of these patents are likely warranted, unmerited patents are a reality of our system and require efficient correction.

This phenomenon arises because the initial patent examination process is not *inter* partes, but

rather *ex parte*, with only the patent applicant present before the Patent Office. Third parties are in fact barred from communicating with the Patent Office regarding pending applications, which is contrary to much of the world that provides for pre-issuance oppositions to pending patent applications. Thus, the patent application process in the United States naturally, and unsurprisingly, results in issuance of many patents that do not stand up under *inter partes* scrutiny. This result has been defended in the literature as, *Rational Ignorance at the Patent Office*. Mark A. Lemley, 95 Northwestern U. L. Rev. 4 (2001).

When improper patents are granted, the cost of pharmaceuticals undoubtedly increases. With even just one unmerited patent, drug corporations have free license to monopolize the market and charge astronomical prices. Excessive costs prevent consumers from receiving necessary care and places a higher burden on taxpayers. A Harvard study found that government insurance programs could have saved $1 billion from 2000 to 2004 if the PTO had not issued inappropriate patent extensions for three drugs. Aaron S. Kesselheim et al., *Extensions of Intellectual Property Rights and Delayed Adoption of Gneeric Drugs: Effects on Medicaid Spending*, 25 Health Affairs 1637 (Nov. 2006). Further, the European Competition Commission noted that the pharmaceutical industry's tactics to delay generic drug versions from immediate entry cost the European Union's healthcare system 3 billion Euros. See European Competition Commission, *Pharmaceutical Sector Inquiry*, July 2009, http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/ .

Two examples based on I-MAK's research are illustrative of these findings. First, Gilead Sciences has pursued unmerited patents for Sovaldi®, its principal hepatitis C drug. In the past 3.5 years, Gilead Sciences made more than $35 billion in the U.S. alone on their portfolio of Sovaldi®-based hepatitis C drugs. I-MAK Policy Brief, *supra*, at 3. While 3.5 million people have Hepatitis C in the United States, 85% of diagnosed individuals did not receive treatment in 2016 and similar is expected for 2017. *See Hepatitis C Kills More Americans than Any Other Infectious disease*, CDC (May 4, 2016), https://www.cdc.gov/media/releases/2016/p0504-hepc-mortality.html. This lack of treatment is largely the result of high drug costs, which result in insurance companies either denying treatment or rationing treatment to the sickest patients. See Senate Finance Committee Report, *The Price of Sovaldi and its Impact on the U.S. Health Care System, December 2015,* https://www.finance.senate.gov/ranking-members-news/wyden-grassley-sovaldi-investigation-finds-revenue-driven-pricing-strategy-behind-84-000-hepatitis-drug

A recent study found Sovaldi® could be manufactured at $101 per treatment, but Gilead Sciences priced the drug at $1,000 per pill or $84,000 for the three-month treatment regimen at the drug's launch. Andrew Hill et al., *Rapid Reductions in Prices for Generic Sofosbuvir and Daclatasvir to Treat Hepatitis C*, 2 J. Virus Eradication 28-31 (Jan. 1, 2016); Margot Sanger-Katz, *Why the Price of Solvadi is a Shock to the System*, N.Y. Times (Aug. 6, 2014), https://www.nytimes.com/2014/08/07/upshot/why-

the-price-of-sovaldi-is-a-shock-to-the-system.html. Unmerited secondary patents will allow Gilead Sciences to continue its monopolization of the market through 2034 even though the science underlying the drug has been in the public domain for decades. Thus, drug pricing is necessarily tied to the patent system and has profound effects on patients' lives.

Second, Abbott Laboratories' ("Abbott") HIV treatment, Kaletra®, is a staggering example of how pharmaceutical corporations spin a never-ending web of secondary patents. Between 1989 and 2012, Abbott filed at least 108 patent applications in the United States for Kaletra®. I-MAK Policy Brief, *supra*, at 5. The majority of these applications do not meet the novel and non-obvious legal requirements under patent law. *Id.* Approximately six of these patents are for the drug's heat-stable formulation technique, which has been well known for decades. *Id.* An additional eight patents are for trivial tweaks to the formulation technique. *Id.* Together, Abbott's Kaletra® patents could delay generic competition until at least 2028 – 12 years after the drug's base compound patents expire and 39 years after the first patents were filed. *Id.* In this manner, pharmaceutical companies can create a thicket of secondary patents around the original compound patent to deter or delay generic competition. This tactic partially drives "pay for delay settlements," where branded companies halt competition by paying generic manufacturers to stay off the market. Accordingly, secondary patents create market monopolies that promote increased profits over reduced consumer costs. Drug prices are undeniably affected.

In a recent study, I-MAK modeled the financial impact of unmerited patents or pay-for-delay settlements blocking the entry of generic products into the market over time. One of the case studies in the paper reviewed the patent landscape for the drug Revlimid®, as sold by Celgene. The study identified that Celgene had over a period of time amassed a total of 76 granted patents and patent applications on the product. This patent estate on Revlimid® is set to run until 2036, providing Celgene with a potential monopoly of 40 years. Reviews of the patents on the grounds of novelty or obviousness showed that these patents are likely unmerited but are being used to delay generic competitors from entering the market. See I-MAK, *America's Overspend, How the Pharmaceutical Patent Problem is Fueling High Drug prices*, October 2017, http://www.i-mak.org/resources/.

B. *Inter Partes* Review is Critical to Lowering Drug Costs.

An effective weapon against the proliferation of unmerited secondary patents is the PTAB. While the PTO (through an individual examiner who is often not an attorney) makes the initial determination to award a patent, the PTAB (through a panel of three administrative judges who are each extremely experienced patent attorneys) operates as a check on the U.S. patent system. Specifically, the PTAB reevaluates challenged patents to ensure the patentability decision conforms to applicable law. Since its creation, the PTAB has reviewed more than 4,500 cases (less than 2% of the number of patents issued every year), and has laid a solid foundation for addressing major national challenges ranging from

high drug prices enabled by unmerited patents to frivolous attempts at monopolizing information shared over email and through podcasts. *See* Jeffrey Ware et al., *Litigation Alert: Supreme Court Leaves Intact PTAB Authority to Institute and Regulate Inter Partes Review Proceedings*, Fenwick & West (June 23, 2016), https://www.fenwick.com/publications/pages/supreme-court-leaves-intact-ptab-authority-to-institute-and-regulate-inter-partes-review-proceedings.aspx. IPR review by the PTAB ensures expeditious and cost-efficient examination of challenged patents. Timely reconsideration is crucial to the elimination of unmerited patents, which, in turn, helps decrease drug prices.

First, IPR review is more expedient than litigation. Litigation is a time-consuming process that often lasts several years. IPR proceedings, on the other hand, are statutorily required to be terminated within 18 months. 37 C.F.R. § 42.100(c). This accelerated timeline suggests a higher likelihood that courts will stay litigation pending the IPR outcome. Further, any appeal must be made directly to the U.S. Court of Appeals for the Federal Circuit, which enables faster appellate resolution. If patent challenges were restricted to judicial forums, it could take years to eliminate unmerited patents and would only be accessible by commercial entities given that only potentially infringing parties have legal standing in the courts. In the meantime, the pharmaceutical company possessing an unwarranted patent would still maintain a monopoly on the drug and benefit from the patent's protections. IPR, therefore, enables unmerited patents to be expeditiously revoked, which, in turn, allows

competitors to enter the marketplace and introduce cheaper generic alternatives.

Additionally, IPR is conducted by a knowledgeable panel of judges who are technical experts and intimately familiar with patent concepts and terminology. Judges of the PTAB are more likely to comprehend the substantive and technical details of the patent claims, and will be better suited to understand complex technology and invalidity arguments. *See id.* Article III judicial decision makers, on the other hand, are unlikely to have the engineering and science background necessary to analyze patents, and may be uncomfortable invalidating patents that they do not fully understand. *Id.* Thus, IPR helps ensure patents are evaluated based on their true validity and compliance with applicable legal elements.

Finally, IPR is a cheaper form of dispute resolution than litigation. Full-blown patent litigation is accompanied by significant legal costs, which are not present with administrative review. PTAB review reduces costs by permitting only limited discovery and establishing a shortened timeframe for a conclusive decision. *See id.* The cost effectiveness of IPR ensures that all challengers have access to this forum and will not be deterred by cost considerations. In turn, this enables generic companies to more frequently challenge unmerited patents, which may promote competition and lower drug prices if those patents are deemed improper. Accordingly, the PTAB is a fundamental check and balance on the PTO's decision to award a patent, and has significant advantages over prolonged litigation.

Therefore, IPR is essential to lowering drug costs through the timely elimination of unmerited and unwarranted patents. The judicial process is ill equipped to provide the most time efficient resolution to complex technical questions of validity.

II. Eliminating *Inter Partes* Review Would Reverse Early Progress Towards Reduced Drug Costs.

Given the benefits associated with IPR and its ability to help curb rising drug prices, it is crucial that the PTAB continue its review of challenged patents. The PTAB's potential to achieve more on behalf of the American public is only beginning to be realized. As a U.S. Government Accountability Office report found, the Patent Office must continue to improve the quality of the patents it is granting. *Patent Office Should Define Quality, Reassess Incentives, and Improve Clarity* (GAO-16-490), GAO (Jun. 30, 2016), https://www.gao.gov/products/GAO-16-490. At the same time, branded drugs – the vast majority of which are protected by clusters of patents – account for more than 70% of total drug spending in the United States. Reuters, *What's to Blame for High U.S. Drug Costs,* NBC News (Aug. 23, 2016, 3:59PM), https://www.nbcnews.com/health/health-news/what-s-blame-high-u-s-drug-costs-n636696. A recent Kaiser Family Health poll found that one in five Americans have chosen not to fill a prescription due to unaffordable prices. *Id.*; I-MAK Policy Brief, *supra*, at 4; *see also* Chris Crawford, *One in Three Patients Not Filling Prescriptions, Study Finds*, AAFP (Apr. 28, 2014, 9:19AM), http://www.aafp.org/news/health-of-the-public/20140428nonadherencestudy.html (finding

that 1/3rd of patents fail to fill first-time prescriptions).

If this Court holds that IPR is unconstitutional, it could prematurely cripple the United States' efforts to curb unmerited patents. 4. Additionally, the Congressionally proposed "Stronger Patents Act" will gut the patent challenge process at the PTAB, effectively "undo[ing] much of the progress that has been made," as House Judiciary Committee Chairman Bob Goodlatte (R-VA) noted at a recent hearing. Ryan Davis, *Patent System in 'Crisis Mode,' Ex-Fed. Circ. Chief Says*, Law360 (July 13, 2017, 10:06 PM), https://www.law360.com/ip/articles/944213. A similar decision by this Court to strip the PTAB of its authority would have a comparable effect.

This Court's holding will not only implicate fundamental questions of constitutional law, but will also directly affect consumers' ability to obtain affordable, lifesaving drugs. A ruling in favor of Petitioners means that the nascent advancements in drug price reductions to date will be unable to achieve their full potential. The United States would lose a major tool for eliminating unmerited patents that are a root driver of high drug costs, and which ensures the integrity of the patent system. Accordingly, the broader implications on the cost of medicines and access favor a finding that IPR is constitutional.

CONCLUSION

For these reasons, the judgment of the Court of Appeals should be affirmed. A contrary holding by this Court could significantly hamper the United

States' ability to assess and remove unmerited patents, and lower the price of lifesaving pharmaceutical drugs.

Respectfully submitted,

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